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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,870	02/28/2001	Xavier Forceville	569J US 3770	3493

466 7590 09/24/2003

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EXAMINER
PAK, JOHN D

ART UNIT	PAPER NUMBER
1616	14

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/763,870	Applicant(s) FORCEVILLE ET AL.	
	Examiner JOHN D PAK	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,24,26,28-36,38,40 and 44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,24,26,28-36,38,40 and 44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

Claims 23-24, 26, 28-36, 38, 40 and 44 are pending in this application.

New prior art references are noted. It is regretted that another non-final Office Action must be issued. After reviewing this Office Action, Applicant is invited to telephone the Examiner to arrange for a telephone interview in order to expedite the further handling of this application.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-24, 26, 30-32, 35-36, 38, 40 and 44 are rejected under 35 USC 102(b) as being anticipated by Southan et al. (WO 96/30007).

Southan et al. explicitly discloses treating systemic inflammatory response syndrome (SIRS), circulatory shock, multiple organ dysfunction syndrome, gram-negative sepsis, and gram-positive sepsis with seleno derivatives (see formulas on pp. 11 and 15) that are inclusive of ASZ, which is 2-aminoselenoazoline (p.16, lines 1-13; Example 12 on pp. 35-36; claims 38, 39). See also p. 9, lines 13-14 for other specific seleno-compounds. For adult humans, the most preferable dosage is 100 mg to 3 g per day, which is, when calculated for ASZ in the case of a 70 kg average adult human, about 0.76 mg of selenium/kg/day to about 22.7 mg of selenium/kg/day. Similar calculations can be made for the lower end of the

broader dosage range, 5 mg ASZ (see e.g., claim 50) which is about 0.038 mg of selenium/kg/day.

Claim 23 recites dosage range of 0.025-1 mg/kg/day. The dosage range explicitly disclosed by Southan et al. clearly ~~are~~ is within applicant's claimed range. Claims 24 and 26 recite various types of SIRS. Southan's disclosure of circulatory shock, multiple organ dysfunction syndrome, gram-negative sepsis, and gram-positive sepsis are clearly within the SIRS types of instant claims 24 and 26. Claim 30 recites specific selenium compounds, but "synthetic chemicals containing one or more atoms of selenium" clearly encompass Southan's ASZ. Claim 31 recites parenteral, intraperitoneal or oral route of administration, but Southan et al. explicitly disclose parenteral and oral routes of administration (see p. 18, lines 7-11). Claim 32 recites an antioxidant or anti-inflammatory compound, but Southan et al. clearly disclose other additives such as an anti-inflammatory (p. 21, lines 22-24).

Claim 35 recites a second treatment of selenium at a daily dosage of about 0.00625-0.025 mg of selenium per kg of body weight. NOTE, however that claim 35, which is an independent claim, does not require that the subject receiving the treatment is a human adult. Southan et al. disclose that the precise amount administered is the responsibility of the attendant physician, wherein said amount depends on a number of factors such as the age/sex of the patient, precise disorder being treated, and its severity (paragraph bridging pages 22 and 23, see claims 50-52). Southan's explicit disclosures as to dosage therefore

encompasses the dosage range claimed in instant claim 35. Second treatment is encompassed as a continuation of the about 0.025 mg/kg/day used in the first treatment, which is well within Southan's ranges, particularly for a heavier patient or patients with less severe attacks; or in the alternative, the second treatment is encompassed by the disclosure that the precise dosage depends on factors such as severity of condition. Since the severity of the condition would have decreased after the first treatment protocol, Southan et al. explicitly discloses lower ranges (p. 22, lines 11-19) for subsequent treatments, which are still within the second treatment dosage ranges of applicant's claim 35.

Claim 36 recites SIRS from bacterial septicemias in a septic shock state. Southan et al. explicitly disclose treating circulatory shock from bacterial sepsis (p. 16, lines 10-11). Claim 38 is met by Southan et al. for the same reason. Claim 40 is met by Southan's dosage ranges given in per day units, which encompasses administering for more than one day. See also above discussion as to the second treatment. Discussions hereinabove also support the explicit disclosure of claim 44.

For these reasons, Southan et al. disclose every claim required feature. See In re Sivaramakrishnan, 213 USPQ 441 (CCPA 1982). The above noted claims are thereby anticipated.

Claims 23-24, 26, 28-36, 38, 40 and 44 are rejected under 35 USC 103(a) as being unpatentable over the combined teachings of Southan et al. and Hofbauer et al. in view of Medline abstract 89114296.

Teachings of Southan et al. have been set forth above, and the discussion there is incorporated herein by reference. In short, Southan et al. disclose selenium compounds at the same dosage amount ranges for SIRS treatment.

Hofbauer et al. teach administering larger loses of selenite for treating inflammatory diseases, e.g. sepsis secondary to pneumonia (see the Summary section on p. 103, left column). 2.5 mg total selenite over a period of seven days is disclosed (p. 104, left column).

Medline abstract 89114296 teaches selenium concentration is decreased in patients with infections such as septicemia, pneumonia and meningitis.

While the cited references do not expressly disclose administering sodium selenite or several different types of selenium compounds, the cited references combine to establish that the ordinary skilled artisan would have been motivated to supply the selenium in several different forms to resupply the decreased concentration in the subject patient in order to treat SIRS. The prior art clearly teaches high dosage amounts for the selenium (see both Southan et al. and Hofbauer et al.). Also, while specific combination with the various antioxidants or gold, as in applicant's claims 33-34, is not explicitly disclosed, the cited Medline abstract establishes that antioxidants such as iron and zinc are also decreased in septicemia, pneumonia and meningitis. Motivation is found there to combine

selenium with at least iron or zinc so that the depleted elements are restored. Motivation to add gold arises from its known anti-inflammatory properties, from Southan's suggestion to add anti-inflammatories, and from the need to reduce inflammation in SIRS.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every feature of the claimed invention has been fairly suggested by the combined teachings of the cited references.

For these reasons, all claims must be refused.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:00 AM to 4:30 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Examiner Pak whose telephone number is (703) 308-4538. The Examiner can normally be reached on Monday through Thursday from 8:00 AM to 5:30 PM. The Examiner can also be reached on alternate Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Thurman Page, can be reached on (703) 308-2927.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

JOHN PAK
PRIMARY EXAMINER
GROUP 1600